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In Reply Refer To: 11S

December 9, 2002

PATIENT CARE SERVICES INFORMATION LETTER

PROTOCOL FOR SHARING VA SPINAL CORD DYSFUNCTION-REGISTRY DATA WITH VA AND NON-VA RESEARCH INVESTIGATORS

1. This information letter describes the protocol by which Department of Veterans Affairs (VA) and non-VA researchers may access data stored in the Spinal Cord Dysfunction (SCD)-Registry database at the Austin Automation Center.

2. The SCD-Registry was developed in 1995, through a cooperative effort between the Veterans Health Administration (VHA) Health Services Research and Development (HSR&D) Service (124), the Paralyzed Veterans of America (PVA), and the Austin Automation Center (AAC). However, VA maintains these records exclusively. VA staff complete registration by entering patients diagnosed with spinal cord injury and disorders applying for or receiving VA health care services. The purpose of the SCD-Registry is to assist clinicians, administrators, and researchers in identifying and tracking services for veterans with spinal cord dysfunction resulting from trauma or diseases. The SCD-Registry can also facilitate clinical, administrative, and research reports for medical center use. Local Veterans Health Information System and Technology Architecture (VistA) SCD-Registries provide aggregate data to the National SCD-Registry database at the Austin Automation Center (AAC).

3. These records contain identifying information including name, scrambled SSN, date of birth, unique record identifiers, and registration date. SCD-Registry information may include registration status, neurologic level of injury, etiology, date of onset, completeness of injury, and annual evaluation dates offered and received. The SCD-Registry Outcomes File has data fields for storing measures of impairment, activity, social role participation, and satisfaction with life. A registrant may have multiple entries in this file. Local medical center's VistA-based SCD-Registry software package interactively functions with several VistA applications. SCD-Registry data transmissions from VA health care facilities to national VA databases housed at the Austin Automation Center transmit using the Department's secure, wide area network.

4. VA and non-VA personnel are bound by all legal and ethical requirements to protect the rights of Research and Development participants, including the confidentiality of information that can be identified with a person (M-3, Chapter 9, subpar 9.14). VHA has an obligation to protect its patients from research risks, including risks to the privacy and confidentiality of patient information. Studies involving identifiable participant information are defined as human research according to federal regulations. Specifically, Institutional Review Boards (IRBs) review proposals to determine whether potential risks to human participants are ethically justified.

5. The process described in this Information Letter to request permission to access data stored in the Spinal Cord Dysfunction (SCD)-Registry database at the Austin Automation Center reflects current VA policy. Access to use of the SCD-Registry is approved by the Spinal Cord Injury and Disorders (SCI&D) Strategic Healthcare Group (SHG) and the National Neurology Director's Office using policies and procedures established by the SCD-Registry Product Improvement Team.

a. ***NOTE:*** *M-3, Chapter 9, subparagraph 9.14b applies to VA personnel who wish to use participant information from other VA facilities for VA approved research projects.* VA personnel may obtain and use medical, technical, and administrative records from other VA facilities as well as those available locally for approved Research and Development purposes. The local VA Institutional Review Board and the facility Director must endorse requests for records from other facilities before submission to the SCD-Registry Product Improvement Team for approval. Before submission of the access request to the SCD-Registry Product Improvement Team, VA personnel must complete VA Form 9957, Timesharing User Access Request, with approving signatures from the initiating supervisor, facility Information Security Officer, and/or the facility director. VA personnel will need to establish or have an ACRS account. An updated VA Form 9957 requesting read access to four MDPPRD.MPD.SAS.SCD files (MDPPRD.MDP.SAS.SCD.ETIOL; MDPPRD.MDP.SAS.SCD.EVAL; MDPPRD.MDP.SAS.SCD.OUTCOMES; and MDPPRD.MDP.SAS.SCD.REG) will be needed and should be attached to the access request. VA personnel must ensure that all necessary countersignatures are provided on VA Form 9957 in Section 4. Investigators receiving support from other institutions must also meet the human research requirements of the funding source.

b. ***NOTE:*** *M-3, Chapter 9, subparagraph 9.14c applies to <u>non-VA personnel</u> who wish to use VA participant information.* Persons not employed by the VA can only be given access to medical and other VA records for Research and Development purposes within the legal restrictions imposed by such laws as the Privacy Act of 1974 and Title 38 United States Code (U.S.C.). Access requests from non-VA personnel will first be forwarded to the VHA Privacy Office for review and approval before further processing. VHA's Privacy Office will provide determinations regarding whether authority exists under the Privacy Act, Health Information Portability and Accountability Act of 1996 Privacy Rule, Title 38 U.S.C., or other authorities for granting information access to non-VA personnel. Submission to the SCD-Registry Product Improvement Team should be made at least ninety days before access is desired. Investigators receiving support from other institutions must meet the human research requirements of the funding source. Requests must be endorsed by the IRB that has a cooperative agreement with a VA facility before being submitted for final approval to the Chief Officer, Research and Development (12) in VA Central Office through the SCD-Registry Product Improvement Team.

6. A written request to the SCD-Registry Office is required for consideration of all access requests. If an investigator requires access to patient specific identifiers, the SCD-Registry Product Improvement Team will consider the merits of the research and whether the request meets the requirements of the Privacy Act and VA confidentiality statutes. The following information should be submitted to the SCD-Registry Coordinator (128N), VASDHCS, 3350 La Jolla Village Drive, San Diego, CA 92161.

a. A formal request (memo or letter) signed by the principal investigator, containing the following:

(1) A one page document describing the project (an Executive Summary or Abstract is acceptable) and a copy of the letter of approval from the VA Research Office or other appropriate research agency.

(2) A copy of the Institutional Review Board approval and/or endorsement for the project.

(3) A completed, signed, and returned Privacy Act and Data Security Statement (see Attachment A).

(4) A tabular listing of specific SCD-Registry variables needed to accomplish the objectives within the approved research protocol and the rationale for their inclusion.

(5) If disclosure of patient Social Security Numbers (SSNs) is required, specific documentation for the need and appropriate security clearances for access to patient identifiable information must be provided. Non-VA personnel would be required to collaborate with a VA employee who is at least five-eighths time in order to use veteran identifiable information. ***NOTE:*** *A signed, current copy of VA Form 9957 indicating the appropriate level of security clearance is required.*

b. The researcher shall be responsible for any costs accrued by VHA for database access or use, and all those costs should be incorporated into the full research proposal. Documentation should be included regarding the management and allocation of these costs. If non-VA personnel were to incur substantial database access and use costs, collaboration with a VA employee who is at least five-eighths time may be required.

7. REFERENCES

a. Common Rule for the Protection of Human Subjects, codified at Code of Federal Regulations (CFR) 16.

b. 38 U.S.C. Sections 7331 through 7334.

c. 38 CFR Sections 17.34 and 17.34a.

d. 48 CFR 46.

e. 21 CFR Parts 50 and 56.

f. 21 CFR 11.

g. Federal Register Volume 66, Number 103, Pages 29209-29212.

h. 56 FR 28001-32 (June 18, 1991).

i. The Privacy Act of 1974 (Title 5 U.S.C. 552).

j. M-3, Part I, Veterans Health Administration Chapter 9.

k. MP-6, Part 1, Chapter 2.

l. M-11, Chapter 16.

m. VHA Directive 6210.

n. Title 5 United States Code Section 552a.

o. Section 903c of the Public Health Service Act (42 U.S.C. 299a-1).

p. Health Information Portability and Accountability Act of 1996.

7. Questions concerning the contents of this Information Letter should be directed to the SCD-Registry Coordinator, at the above address or by calling (858) 642-6277.

Thomas V. Holohan, M.D., F.A.C.P.
Chief Patient Care Officer

DISTRIBUTION: CO: E-mailed 12/11/02
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ATTACHMENT A

SAMPLE OF
PRIVACY ACT AND DATA SECURITY STATEMENT
FOR RESEARCH, AUDIT, AND EVALUATION ACTIVITIES INVOLVING RELEASE OF IDENTIFIABLE PATIENT DATA GOVERNED BY THE PRIVACY ACT, TITLE 38 UNITED STATES CODE (U.S.C.) 5701 AND/OR U.S.C. 7332

1. Title of Research, Audit or Evaluation Activity:

2. Patient Data Elements to Be Used:

3. Name(s) of Database(s) for Which Access is Required:

4. Delimiting Dates of Access for Research, Audit or Evaluation Activity:

5. Limitation on Use and Redisclosure: All identifying data will be kept strictly confidential by the Department of Veterans Affairs (VA) and non-VA personnel and will be used only for the research, audit, or evaluation purposes described herein. At the end of the project, all data files with veteran identifiers will be erased or destroyed. Results generated from this research, audit, or evaluation containing identifiers may be disclosed only back to VA, and no identity will be made of any individual patient in any report of the research, audit, or evaluation or otherwise disclose patient identifiers.

6. Data Security: Data containing patient names or identifiers will be securely stored and protected from theft by the use of passwords (when data are stored on hard disks) and locked cabinets (when the data are stored on floppy disks or any other transportable medium). Patient level data will not be disclosed, copied, or transmitted in total or in part to anyone not connected with the approved protocol.

7. Penalty Provisions: Penalties for misuse of the data provided is set at not more than $5,000 for the first offense and not more than $20,000 in the case of any subsequent offense. (5 U.S.C. 552a, 38 Code of Federal Regulations (CFR) 1.576 (e) and 1.463).

CERTIFICATION: As principal investigator, I hereby acknowledge that I am responsible for the research data and understand and agree to the provisions as set forth above. I am responsible for ensuring all individuals participating in this investigation study comply with the provisions as set forth above. This release of identifying patient information is approved, only for the purposes and under the conditions described above, under the provisions of the Privacy Act, 5 U.S.C. 552a(a)(8)(B)(ii) and (b)(3), and routine use #15 as set forth in the VA System of Records Notice. "24VA136, Patient Treatment Records" and 38 U.S.C. 5701 (e) and 38 U.S.C. 7332(b)(2)(B) and VA regulations 38 CFR 1.488 through 1.489.

RESPONSIBLE RESEARCH OFFICIAL(S)

Name(s):
Title(s):
Address(es):
Phone Number(s):
Signature(s) and Date(s):

REVIEWING AND APPROVING VA OFFICIALS

Name:
Title: SCD-Registry Coordinator (128N)
Business Address: VASDHCS, 3350 La Jolla Village Drive, San Diego, CA 92161
Telephone Number: (858) 642-6277

Date: